IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

(Filed: October 26, 2007)

DO NOT PUBLISH

JODI LYNN KABAT,	)	
	)	
Petitioner,	)	
	)	
v.	)	No. 99-0438V
	)	Hepatitis B vaccine; Seizure Disorder
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
	)	
Respondent.	)	
	)	

DECISION[1]

Petitioner, Jodi Lynn Kabat (Ms. Kabat), seeks compensation under the National Vaccine Injury Compensation Program (Program).[2] Ms. Kabat suffers a seizure disorder. *See, e.g.*, Petitioner's exhibit (Pet. ex) 14 (Ms. Kabat's June 14, 2006 Affidavit); 5 (NYU Comprehensive Epilepsy Center records); 20 (NewYork-Presbyterian Hospital Comprehensive Epilepsy Center records). Ms. Kabat relates her seizure disorder to a Hepatitis B vaccination that she received on June 25, 1993. *See, e.g.*, Petition (Pet.); Pet. ex. 21 (Medical Expert Opinion from Robert M. Paschall, D.O.).

[1] As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" will be available to the public. *Id.*

[2] The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-10 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

The special master convened a hearing. Ms. Kabat; Jill Kabat (Mrs. Kabat), Ms. Kabat's mother; and Robert M. Paschall, D.O. (Dr. Paschall),[3] testified during Ms. Kabat's case-in-chief. Michael E. Cohen, M.D. (Dr. Cohen),[4] testified during respondent's rebuttal case.

THE STATUTORY SCHEME

Ms. Kabat may pursue potentially three legal theories. Ms. Kabat may present what is commonly referred to as a Table case. The Act contains the Vaccine Injury Table that lists vaccines covered by the Act and certain injuries and conditions that may stem from the vaccines. *See* § 300aa-14; 42 C.F.R. § 100.3(a). If Ms. Kabat establishes by the preponderance of the evidence that following her June 25, 1993 Hepatitis B vaccination, she suffered the onset of an injury listed on the Table for Hepatitis B vaccine, within the time period provided by the Table for the injury, then she is entitled to a presumption that the vaccine caused the injury. §§ 300aa-11(c)(1)(C)(I); 300aa-13(a)(1)(A).[5] Anaphylaxis/anaphylactic shock is the only injury listed on the Table for Hepatitis B vaccine. 42 C.F.R. § 100.3(a)(VIII)(A). The first symptom or manifestation of onset of anaphylaxis/anaphylactic shock must occur within four hours after the administration of a Hepatitis B vaccination for anaphylaxis/anaphylactic shock to qualify for a presumption of causation. *Id.*

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[3] Dr. Paschall received a degree in osteopathic medicine from the Philadelphia College of Osteopathic Medicine in 1979. *See* Pet. ex. 22 at 1. He completed a residency in neurology at Temple University Hospital, in Philadelphia, Pennsylvania, in 1983. *See id.* He maintains a practice in neurology at Eastern Shore Physicians & Surgeons, in Nassawadox, Virginia. *See* Pet. ex. 22 at 2. In addition, he holds an academic appointment as a clinical assistant professor of neurology at the Medical College of Virginia, in Richmond, Virginia. *See id.* He is certified in neurology by the American Board of Psychiatry and Neurology. *See* Pet. ex. 22 at 1.

[4] Dr. Cohen received his medical degree from the State University of New York at Buffalo (SUNYAB) in 1961. *See* Respondent's exhibit (R. ex.) B at 1. In 1965, he completed a residency in neurology at the University Hospitals in Cleveland, Ohio. *See* R. ex. B at 2. He served as a Fellow in pediatric neurology at the Children's Hospital Medical Center, in Boston, Massachusetts, from 1965 to 1966. *See id.* Since 1983, he has held an academic appointment as a professor of neurology and pediatrics at SUNYAB. *See* R. ex. B at 1. He maintains an active practice in child neurology. *See* Transcript (Tr.I), filed July 6, 2007, at 104-05. He is certified in neurology with special competence in child neurology by the American Board of Psychiatry and Neurology and in electroencephalography by the American Board of Qualification in Electroencephalography. R. ex. B at 3.

[5] The preponderance of the evidence standard requires the special master to believe that the existence of a fact is more likely than not. *See In re Winship,* 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring) (quoting F. JAMES, CIVIL PROCEDURE 250-51 (1965)). Mere conjecture or speculation will not meet the preponderance of evidence standard. *See Centmehaiey v. Secretary of HHS*, 32 Fed. Cl. 612, 624 (1995), *aff'd*, 73 F.3d 381 (1995).

Respondent may rebut the presumption of causation if respondent establishes by the preponderance of the evidence that the injury was "due to factors unrelated to the administration of" a vaccine. § 300aa-13(a)(1)(B); *Knudsen v. Secretary of HHS*, 35 F.3d 543, 547 (Fed. Cir. 1994).

In the alternative, Ms. Kabat may show based upon traditional tort standards that her June 25, 1993 Hepatitis B vaccination caused actually a condition that is listed on the Table for Hepatitis B vaccine, but that occurred outside the period provided in the Table, § 300aa-11(c)(1)(C)(ii)(II); or that her June 25, 1993 Hepatitis B vaccination caused actually a condition that is not listed on the Table for Hepatitis B vaccine. § 300aa-11(c)(1)(C)(ii)(I). The United States Court of Appeals for the Federal Circuit (Federal Circuit) endorses the Restatement (Second) of Torts as a "uniform approach" to resolving actual causation issues in Program cases. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1351 (Fed. Cir. 1999). Thus, to prevail, Ms. Kabat must demonstrate by the preponderance of the evidence that (1) "but for" the administration of her June 25, 1993 Hepatitis B vaccination, she would not have been injured, and (2) her June 25, 1993 Hepatitis B vaccination was "a 'substantial factor' in bringing about" her injury. *Id.* at 1352, citing Restatement (Second) of Torts § 431.

While "[t]he Act relaxes proof of causation for injuries satisfying the Table," the Act "does not relax proof of causation in fact for non-Table injuries." *Grant v. Secretary of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Therefore, the simple temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove actual causation. *See id.* at 1148-50. Rather, long-standing, well-established Federal Circuit precedent instructs that a petitioner establishes a *prima facie* actual causation case by adducing "preponderant evidence" of: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also Capizzano v. Secretary of HHS*, 440 F.3d 1317, 1324 (Fed. Cir. 2006); *Knudsen*, 35 F.3d at 548, citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993); *Grant*, 956 F.2d at 1148. The "*prima facie* case" is "a party's production of enough evidence to allow the fact-finder to infer the fact at issue and rule in the party's favor." BLACK'S LAW DICTIONARY 1228 (8th ed. 2004).

If a petitioner mounts a *prima facie* actual causation case, respondent may present rebuttal evidence. In respondent's rebuttal case, respondent may contest perhaps a petitioner's medical theory through medical expert testimony. Or, respondent may challenge perhaps the factual assumptions that a petitioner's expert adopts in rendering an opinion. Then, the special master weighs all of the evidence to determine if a petitioner has met the evidentiary burden on the merits of the actual causation case.

However, a petitioner does not gain Program compensation upon proving successfully the merits of the petitioner's actual causation case. *See Grant*, 956 F.2d at 1149. The Vaccine Act requires specifically the special master to "also determine that 'there is not a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine,'" or

"alternative etiologies." *Grant*, 956 F.2d at 1149, citing § 300aa-13(a)(1). The Vaccine Act provides that "factors unrelated to the administration of the vaccine," or alternative etiologies

> may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

§ 300aa-13(a)(2)(B). The Vaccine Act provides also that "factors unrelated to the administration of the vaccine," or alternative etiologies, do not encompass "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." § 300aa-13(a)(2)(A).

The Federal Circuit has decreed that the burden of proving alternative actual causation rests squarely with respondent. *See, e.g.*, *Walther v. Secretary of HHS*, 485 F.3d 1146 (Fed. Cir. 2007); *Althen*, 418 F.3d at 1281-82; *Knudsen*, 35 F.3d at 547, citing *Whitecotton v. Secretary of HHS*, 17 F.3d 374, 376 (Fed. Cir. 1994). In addition, the Federal Circuit has decreed that "the standards that apply to a petitioner's proof of actual causation in fact" are "the same as those that apply to the government's proof of alternative actual causation in fact." *Knudsen*, 35 F.3d at 549. Thus, respondent establishes a *prima facie* alternative actual causation case by adducing "preponderant evidence" of: "(1) a medical theory causally connecting the [factor unrelated to the administration of the vaccine] and the injury; (2) a logical sequence of cause and effect showing that the [factor unrelated to the administration of the vaccine] was the reason for the injury; and (3) a showing of a proximate temporal relationship between [the factor unrelated to the administration of the vaccine] and injury." *Althen*, 418 F.3d at 1278; *see also Capizzano*, 440 F.3d at 1324; *Knudsen*, 35 F.3d at 548, citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993); *Grant*, 956 F.2d at 1148.

BACKGROUND

The parties do not dispute the material facts. Ms. Kabat was born on April 16, 1976. *See, e.g.*, Pet. ex. 4 at 1. Ms. Kabat's medical history preceding June 25, 1993, is not relevant. *See, e.g.*, Transcript (Tr.II), filed September 24, 2007, at 8, 13. On June 25, 1993, at age 17 years, Ms. Kabat presented to her pediatrician for a routine physical examination. *See* Pet. ex. 10 at 13 ("W[ell]C[hild]P[hysical]E[xamination]W[ithin]N[ormal]L[imits]"). She received a Hepatitis B vaccination. *See* Pet. ex. 10 at 9-10.

While driving a vehicle on June 29, 1993, Ms. Kabat experienced a seizure that her passenger observed. *See* Pet. ex. 1 at 5, 7; Tr.I at 41. Ms. Kabat does not recall the event. *See* Tr.I at 34-35, 42. Ms. Kabat remembers only waking briefly "in the ambulance" that transported her to Good Samaritan Hospital in Suffern, New York, and waking again "in the hospital," where she learned that she "had a seizure." Tr.I at 34-35; *see also* Pet. ex. 1 at 5, 7. However, based upon the passenger's description of Ms. Kabat's behavior, Stuart Lestch, M.D. (Dr. Lestch), a neurologist who evaluated

Ms. Kabat upon her admission to Good Samaritan Hospital, concluded that Ms. Kabat had exhibited a "tonoclonic seizure" accompanied by "staring," possible aphasia and "tongue[-]biting." Pet. ex. 1 at 7; *see also* Pet. ex. 1 at 5.

Ms. Kabat remained in the hospital overnight. *See* Pet. ex. 1 at 7-8; Tr.I at 36. Ms. Kabat recounted that she "didn't feel well at all," sleeping "20 hours right after the seizure." Tr.I at 35. In addition, Ms. Kabat recounted that "everything hurt." *Id.*; *see also* Pet. ex. 1 at 7 ("Since awakening[, Ms. Kabat] complained of bifrontal headaches."). Further, Ms. Kabat recounted that she "was disoriented." Tr.I at 36. Dr. Paschall and Dr. Cohen confirmed that the length and the character of Ms. Kabat's postictal period is typical of the postictal period following an initial seizure. *See* Tr. at 73, 91-93, 113.

During Ms. Kabat's hospitalization, Dr. Lestch performed a number of diagnostic procedures. *See generally* Pet. ex. 1 at 3, 7-9. At the outset, Dr. Lestch determined that Ms. Kabat's physical and neurological examinations were "normal." Pet. ex. 1 at 7. In addition, Dr. Lestch noted that a "[n]on[-]contrast cat scan of the brain;" a "cervical spine x-ray;" a "C[omplete]B[lood]C[ount];" Ms. Kabat's "chemistries;" and an electrocardiogram were "normal." Pet. ex. 1 at 7; *see also* Pet. ex. 1 at 3. However, Dr. Lestch depicted Ms. Kabat's "E[lectro]E[ncephalo]G[ram]" as "abnormal," demonstrating "irritative seizures from the right temporal area." Pet. ex. 1 at 7; *see also* Pet. ex. 1 at 9.

Dr. Lestch discharged Ms. Kabat from the hospital on June 30, 1993, with a "final diagnosis" of "seizure of undetermined etiology." Pet. ex. 1 at 7. Dr. Lestch prescribed "Tegretol." Pet. ex. 1 at 8. Dr. Lestch intended to monitor Ms. Kabat "as [an] outpatient." *Id.* Dr. Lestch recommended an "outpatient M[agnetic]R[esonance]I[maging]" study. *Id.*

On July 7, 1993, Andrew Schechter, M.D. (Dr. Schechter), performed an MRI of Ms. Kabat's "brain." Pet. ex. 1 at 10. Dr. Schechter found "no evidence of abnormal signal intensity or mass effect." *Id.* Dr. Schechter interpreted the MRI as "[n]ormal." *Id.*

Ms. Kabat estimates that since June 30, 1993, she has suffered 11 seizures. *See* Tr.I at 38-39. Some of Ms. Kabat's seizures occurred when Ms. Kabat did not comply with her medication regimen. *See* Pet. ex. 14 at 1; *see also* Pet. ex. 2 at 4. Some of Ms. Kabat's seizures occurred when Ms. Kabat's treating neurologists were adjusting Ms. Kabat's "dosage of tegretol" to achieve a therapeutic level of the antiepileptic medication. *See* Pet. ex. 14 at 1; *see also* Pet. ex. 3 at 6-7; Pet. ex. 9 at 16-17; Pet. ex. 11 at 30. Some of Ms. Kabat's seizures occurred when Ms. Kabat's treating neurologists attempted to wean Ms. Kabat from Tegretol and to institute "Topomax and Kepra." Pet. ex. 14 at 1; *see also* Pet. ex. 6 at 9-10; Pet. ex. 15 at 3; Pet. ex. 20 at 9-11. However, Ms. Kabat testified that she has not experienced any seizures since 2002. *See* Tr.I at 41. Regardless, Ms. Kabat said that she expects to continue Tegretol for "the rest of [her] life." Tr.I at 40. And, according to Ms. Kabat, her treating neurologists have counseled her that extended use of Tegretol includes the risk of several "serious" side effects, such as "birth defects" and liver toxicity. Tr.I at 39. Yet, Ms. Kabat is able to participate in a full range of activities of daily living. *See, e.g.*, Tr.I at 30 (Ms. Kabat

works and attends "school."). Indeed, Ms. Kabat anticipates that in December 2007, she will receive her master's degree in elementary education from the University of Hartford, in Hartford, Connecticut. *See* Tr.I at 30.

DISCUSSION

Ms. Kabat does not allege that she suffered anaphylaxis/anaphylactic shock within four hours after her June 25, 1993 Hepatitis B vaccination. *See, e.g.*, Pet. ex. 21. Therefore, Ms. Kabat is not entitled to any presumption of causation afforded by the Table. Instead, Ms. Kabat pursues her case under an actual causation theory. Ms. Kabat relies upon Dr. Paschall's opinion to establish her claim.

The special master limits his discussion to his evaluation of Dr. Paschall's opinion. The special master observed carefully Dr. Paschall during thorough direct examination, cross-examination and rebuttal examination. The special master interrogated intently Dr. Paschall. The special master has assessed comprehensively his impressions of Dr. Paschall's testimony. The special master has balanced critically Dr. Paschall's opinion against Ms. Kabat's medical records. The special master decides that Dr. Paschall grounds his opinion in an unsupported–and, ultimately, incorrect–assertion of fact. Therefore, the special master determines that Dr. Paschall's opinion is inherently flawed. As a consequence, the special master concludes that Dr. Paschall's opinion does not establish Ms. Kabat's evidentiary burden.

Dr. Paschall concedes that a "direct link" between Hepatitis B vaccine and seizures "does not exist." Tr.I at 59; *see also* Tr.I at 82; Pet. ex. 21 at 3 ("Please be aware that there is no association of hepatitis B vaccination with epilepsy *per se*."). Likewise, Dr. Paschall concedes that "[e]pilepsy does tend to appear at age 17 in its idiopathic form." Pet. ex. 21 at 4; *see also* Tr.I at 83, 94-95. Thus, Dr. Paschall identifies a "conundrum" in the case. Pet. ex. 21 at 4; *see also* Tr.I at 76. To resolve his conundrum, Dr. Paschall constructs a conceit. *See, e.g.*, Tr.I at 59 (Dr. Paschall inserts "an intermediate step" in the evolution of Ms. Kabat's seizure disorder.). In Dr. Paschall's view, Ms. Kabat's seizure on June 29, 1993, was not simply the common "appearance of a seizure disorder *de novo* in a 17-year-old." Pet. ex. 21 at 4; *see also* Tr.I at 82-83, 94. Rather, in Dr. Paschall's view, Ms. Kabat's seizure on June 29, 1993, represented the manifestation of a broader neurologic condition: acute disseminated encephalomyelitis (ADEM). *See generally* Pet. ex. 21; Tr.I at 44-97. As Dr. Paschall formulates the case, Ms. Kabat's June 25, 1993 Hepatitis B vaccination caused a "site-specific" or "focal" ADEM, producing "brain scarring," prompting a seizure, leading to Ms. Kabat's seizure disorder. Tr.I at 59; *see also* Tr.I at 50-51, 56-58, 70-71, 87, 90.

Dr. Paschall defines ADEM as a "white matter disease," Tr.I at 78; *see also* Tr.I at 85-87, that is usually "monophasic." Tr.I at 68. In contrast, Dr. Paschall acknowledges that a seizure arises from an abnormality in gray matter. *See, e.g.*, Tr.I at 146-47. Dr. Paschall offers that the "spectrum" for ADEM ranges "from mild to severe to death." Tr.I at 49; *see also* Tr.I at 60, 70, 86-88. Dr. Paschall states that typical clinical features of ADEM include fever, *see* Tr.I at 77; motor

impairment; "cognitive impairment" and seizures. Tr.I at 86. Dr. Paschall explains that seizures occur in ADEM when white matter destruction affects gray matter. *See* Tr.I at 144-47. Dr. Paschall states that typical laboratory features of ADEM include "high" levels of "protein" in "spinal fluid," Tr.I at 85-86; *see also* Tr.I at 90; and "an abnormal MRI scan." Tr.I at 85; *see also* Tr.I at 90. According to Dr. Paschall, ADEM is rare. *See* Tr.I at 49, 67-68. In fact, Dr. Paschall asserts that in the clinical setting, ADEM "gets [one's] attention quickly." Tr.I at 68.

The statute enacting the Program instructs a special master to "consider. . . any diagnosis, conclusion, [or] medical judgment. . . which is contained in the record regarding the nature, [or] causation. . . of the petitioner's illness, disability, injury, [or] condition" and "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 300aa-13(b)(1). As the Federal Circuit has remarked, "treating physicians are likely to be in the best position to" appreciate the clinical significance of a particular patient's presentation. *Capizzano*, 440 F.3d at 1326. Dr. Lestch is ostensibly a qualified neurologist. Upon reviewing Ms. Kabat's emergent symptoms on June 29, 1993, and upon examining Ms. Kabat on June 29, 1993, Dr. Lestch did not discover apparently anything to cause him to suspect that Ms. Kabat was exhibiting a white matter disease. Rather, Dr. Lestch deemed Ms. Kabat's neurologic examination to be "normal." Pet. ex. 1 at 7. Thus, Dr. Lestch determined that Ms. Kabat had suffered only a "seizure of undetermined etiology." *Id.* Based upon Dr. Paschall's pronouncement that a physician would not mistake likely the manifestations of ADEM, *see* Tr.I at 68, Dr. Lestch's actions are entirely consistent with a factual conclusion that Ms. Kabat did not sustain ADEM in June 1993.

Indeed, Dr. Paschall admits necessarily that Ms. Kabat's medical records do not reflect any evidence of white matter disease. *See* Tr.I at 68 (no "MRI findings"); 72 (normal neurologic examination); 75 (no treatment with steroids or IVIG); 78-79 ("no signs of inflammation" or other evidence of white matter disease); 95 (no clinical manifestations of white matter disease), 147-49 ("no picture" of white matter disease). Nonetheless, Dr. Paschall charges forward, maintaining that Dr. Lestch did not perform an adequate investigation of Ms. Kabat's condition during Ms. Kabat's hospitalization in June 1993. *See* Tr.I at 52, 75-76, 78, 80, 95, 148. Dr. Paschall proclaims confidently that had Dr. Lestch obtained a spinal tap or pursued "serial scans," Dr. Lestch "would have found" signs of white matter disease. Tr.I at 78. So, Dr. Paschall insists, his "evidence for ADEM" in this case "is that [Ms. Kabat] didn't have the proper workup to prove that she had ADEM." Tr.I at 80; *see also* Tr.I at 78, 148. Yet, as Dr. Paschall grants, he has "neither proof" that Ms. Kabat sustained ADEM in June 1993 "nor. . . proof" that Ms. Kabat did not sustain ADEM in June 1993. Tr.I at 148. All bluster aside, Dr. Paschall's stance that Ms. Kabat suffered ADEM in June 1993 amounts to nothing more than pure speculation.

Dr. Paschall advances another, similarly circular and illogical proposition in this case. Dr. Paschall agrees certainly that "[e]pilepsy does tend to appear at age 17 in its idiopathic form." Pet. ex. 21 at 4; *see also* Tr.I at 83, 94-95. But, Dr. Paschall attempts to distinguish Ms. Kabat's seizure disorder from idiopathic epilepsy because Ms. Kabat received a Hepatitis B vaccination four days before her first seizure. *See* Tr.I at 82, 91, 94, 148. According to Dr. Paschall, a child who suffers the onset of a seizure disorder in the absence of vaccination represents "a routine idiopathic seizure

case," Tr.I at 82-83; *see also* Tr.I at 94, while a child who suffers the onset of a seizure disorder following vaccination represents a case of ADEM, even without other evidence of white matter disease. *See* Tr.I at 82-83, 91, 94, 148. Under Dr. Paschall's rationale, there would never be a case of idiopathic epilepsy following vaccination. The special master is not impressed that Dr. Paschall's proposition is medically sound.

CONCLUSION

After canvassing the record as a whole, the special master rejects as unsupported and incorrect Dr. Paschall's fundamental premise that Ms. Kabat suffered ADEM in June 1993. Ms. Kabat recognizes clearly that the special master's factual finding that Ms. Kabat did not suffer ADEM in June 1993 renders the remainder of Dr. Paschall's opinion moot. *See* Tr.II at 6. Therefore, the special master rules that Ms. Kabat is not entitled to Program compensation. In the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment dismissing the petition.

s/John F. Edwards
John F. Edwards
Special Master